104. The drugs manufactured by Dey and covered by Medicare Part B include, but may not be not limited to: albuterol sulfate, acetylcysteine, cromolyn sodium, ipratropium bromide, and metproterenol sulfate.

105. Defendant Dey, Inc. f/k/a Dey Laboratories, Inc. ("Dey") is a corporation organized under the laws of Delaware with its principal offices in Napa, California.

106. Dey is a specialty pharmaceutical company focusing on drug products for respiratory diseased and related allergies. The products it manufactures and publishes AWPs on include: Ipratropium, Bromide; Metapeoterenol Sulfate, and Accuneb.

11. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)

107. Defendant Fujisawa Healthcare, Inc. ("Fujisawa Healthcare") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois, 60015. Fujisawa Healthcare is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd., a Japanese corporation. Fujisawa Healthcare focuses its efforts in the therapeutic areas of immuno-suppression and transplantation, cardiovascular care, skin care, oncology, and antifungal and anti-infective treatment.

108. Defendant Fujisawa USA, Inc. ("Fujisawa USA") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois. Fujisawa USA was a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd. In 1998, Fujisawa Healthcare assumed responsibility for Fujisawa USA's portfolio of proprietary products

109. The drugs manufactured by Fujisawa Healthcare and Fujisawa USA (collectively referred to as "The Fujisawa Group") and covered by Medicare Part B include, but may not be limited to: Acyclovir Sodium, Dexamethasone Sodium Phosphate, Doxorubicin Hydrochloride, Fluorouracil, Gentamicin Sulfate, Pentamidine Isethionate, and Vancomycin Hydrochloride.

12. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

110. Defendant GlaxoSmithKline, P.L.C. ("GlaxoSmithKline") is a public limited company incorporated under the laws of England and Wales, with its corporate headquarters located at 980 Great West Road, Brentford, Middlesex, United Kingdom TW8 9GS. GlaxoSmithKline was created through the December 27, 2000, merger of GlaxoWellcome, P.L.C. and SmithKline Beecham, P.L.C. GlaxoSmithKline's operational headquarters are located at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

111. Defendant SmithKline Beecham Corporation ("SKB"), a wholly-owned U.S. subsidiary of the former SmithKline Beecham P.L.C., is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

112. Defendant GlaxoWellcome, Inc. ("Glaxo"), a wholly-owned subsidiary of GlaxoSmithKline, is a North Carolina corporation with its principal place of business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina. Cerenex Pharmaceuticals ("Cerenex"), a division of Glaxo prior to the merger, was responsible for Glaxo's central nervous system drugs, including Zofran.

113. Defendants GlaxoSmithKline, SKB and Glaxo are referred to collectively as the "GSK Group."

114. The GSK Group is a diversified pharmaceutical company which controls an estimated 7 percent of the world's pharmaceutical market. In 2001, the GSK Group reported pharmaceutical sales of $24.8 billion.

115. The drugs manufactured by the GSK Group and covered by Medicare Part B include, but may not be limited to: Hycamtin® (topotecan hydrochloride), Ventolin® (albuterol) and Zofran® (ondansetron hydrochloride). Pierre Fabré Médicament licenses another Medicare Part B drug, Navelbine® (vinorelbine tartrate), to the GSK Group. SmithKline Beecham P.L.C. manufactured and sold Kytril® (granisteron hydrochloride), another drug covered by Medicare

Part B (and a competitor to Zofran®), prior to the merger. To secure regulatory approval for the merger, SmithKline Beecham P.L.C. sold Kytril®'s global rights to the Roche Group in December of 2000.

116. GSK is also sued herein as a member of the Together Rx conspiracy.

13. Immunex

117. Defendant Immunex Corporation ("Immunex"), a wholly owned subsidiary of Defendant Amgen, Inc., is a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington. Immunex is a company that develops products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. In 1999, its total revenues were $542 million.

118. Immunex is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceutical drugs that are manufactured by Immunex and covered by Medicare Part B include, but may not be limited to: Leucovorin Calcium, Enbrel® (etanercept), Novantrone® (mitoxane hydrochloride), Leukine® (sargramostim), and Thioplex®(thiotepa).

119. Defendant Immunex has been a wholly owned subsidiary of Defendant Amgen, since Immunex' acquisition in July 2002.

14. The Johnson & Johnson Group (J&J, Centocor, Janssen, NcNeil, Ortho)

120. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. In 2001, pharmaceutical sales represented 45% of J&J's worldwide sales and 19% of its operational growth. J&J is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

121. Defendant Centocor, Inc. ("Centocor") is a Pennsylvania corporation and has been a wholly owned subsidiary of Defendant J&J since its acquisition by J&J in October 1999.

Centocor's principal place of business is located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor manufactures, markets and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

122. Defendant Janssen Pharmaceutica Products, L.P. ("Janssen") is a New Jersey limited partnership with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is a subsidiary of Johnson & Johnson. Janssen is sued for its role in the Together Rx conspiracy.

123. Defendant McNeil-PPC, Inc., is a New Jersey corporation. McNeil-PPC, Inc. is a subsidiary of Johnson & Johnson. McNeil Consumer & Specialty Pharmaceuticals is a division of McNeil-PPC, Inc. and has a principal place of business located at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. McNeil-PPC is sued for its role in the Together Rx conspiracy.

124. Defendant Ortho Biotech ("Ortho") is New Jersey corporation and has been a wholly owned subsidiary of Defendant J&J since its formation by J&J in 1990. Ortho's principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey. Ortho manufactures and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

125. The drugs manufactured by J&J, Centocor, Ortho, McNeil-PPC and Janssen (collectively referred to as "J&J Group") and covered by Medicare Part B include, but may not be limited to: ReoPro® (abciximab), an anti-blood clotting medication, Retavase® (reteplase), an anti blood clotting agent, Procrit® (epoetin alfa), for the treatment of anemia, Leustatin® (cladribine), for the treatment of leukemia, Orthoclone® (muromonab-CD3), used to prevent organ transplant rejection, Sporanox® (itraconazole), used in the treatment of fungal infections, and Remicade® (infliximab), an anti-inflammatory drug.

15. Pfizer, Inc.

126. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues, or market capitalization.

127. Pfizer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by the Pfizer Group and covered by Medicare Part B include, but may not be limited to: Cerebyx® (fosphenytoin sodium injection), Dilatin® (phenytoin), Diflucan® (fluconazole), Zithromax® (azithromycin), Trovan® (trovafloxacin mesylate), and Unasyn® (ampicillin sodium/sulbactam sodium).

128. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, the Pfizer Group also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

16. The Pharmacia Group (Pharmacia and Pharmacia & Upjohn)

129. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business located at 100 Route 206, North Peapack, New Jersey. Pharmacia was created through the merger of Defendant Pharmacia and Upjohn, Inc. and Monsanto Company on March 31, 2000.

130. Defendant Pharmacia & Upjohn, Inc. ("P&U") is a subsidiary of Pharmacia Corp. In 1995, P&U was formed through the merger of Pharmacia AB and The Upjohn Company. P&U became a global provider of human healthcare products, animal health products, diagnostics and specialty products. In 1998, Pharmacia & Upjohn relocated its global headquarters from the United Kingdom to New Jersey. In September 1999, the company established its global headquarters on a 70-acre campus in Peapack, New Jersey. This site is now the management and pharmaceutical headquarters for Pharmacia.

131. Pharmacia is a highly diversified health care company whose business focuses on the discovery, development, manufacture and sale of a broad and diversified line of health care products and services, including pharmaceuticals, diagnostics and hospital products. Pharmacia's Prescription Pharmaceuticals business segment is involved in researching, developing, registering, manufacturing and selling prescription pharmaceutical products, including general therapeutics, ophthalmology, and hospital products, which include oncology products and diversified therapeutics. Pharmacia reported sales of $18.1 billion for the fiscal year ended December 31, 2000. Pharmacia also reported $12.0 billion in prescription pharmaceuticals sales for the year 2001, and $10.8 billion in prescription pharmaceuticals sales for the year 2000. Prescription pharmaceuticals sales account for over 85 percent of Pharmacia's overall pharmaceutical sales. According to its Annual Report, Pharmacia's oncology drugs generated more than $1 billion in sales in 2001.

132. The drugs manufactured by Pharmacia and P&U (collectively referred to as "The Pharmacia Group") and covered by Medicare Part B include, but may not be limited to: Adriamycin PFS® (doxorubicin hydrochloride), Adrucil® (fluorouracil), Amphocin® (amphotericin), Aromasin® (bleomycin), Camptosar® (irinotecan hydrochloride), Cleocin Phosphate® (clindamycin phosphate), Neosar ® (cyclophosphamide), Cytosar-U (cytarabine), Depo-Testosterone® (testosterone cypionate), Adriamycin PFS® (doxorubicin HCL), Ellence® (epirubicin HCL), Toposar® (etoposide), Adrucil® (fluorouracil), Solu-Cortef® (hydrocortisone sodium succinate), Idamycin® (idarubicin hydrochloride), Medrol® (methylprednisolone), and Vincasar® (vincristine sulfate).

17. The Schering-Plough Group (Schering Plough & Warrick)

133. Defendant Schering-Plough Corporation ("Schering-Plough") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

134. Schering-Plough's primary business involves prescription products in core product categories, including allergy and respiratory, anti-infective and anticancer, cardiovasculars, dermatologicals and central nervous systems and other disorders. Schering-Plough's revenues in 2001 totaled $9.8 billion.

135. Defendant Warrick Pharmaceuticals Corporation ("Warrick"), is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada. Warrick is a wholly-owned subsidiary of Defendant Schering-Plough and has been since its formation in 1993. Warrick manufactures generic pharmaceuticals.

136. The drugs manufactured by Schering-Plough and Warrick (collectively at times referred to as "The Schering-Plough Group") and covered by Medicare Part B include, but may not be limited to: Proventil® (albuterol sulfate), Integrelin® (eptifibatide), Intron A® (interferon alfa-2b recombinant), and Temodar® (temozolomide). The Schering-Plough Group's Albuterol sulfate sales alone totaled $154 million in 2000.

18. The Sicor Group (Sicor and Gensia)

137. Defendant Sicor, Inc. ("Sicor") is a Delaware corporation with its principal place of business located at 19 Hughes, Irvine, California. Sicor was the result of the 1997 merger between Defendant Gensia, Inc. ("Gensia"), a finished dosage manufacturer, and Rakepoll Holding, a Europe-based supplier of active pharmaceutical ingredients.

138. Sicor markets itself as a vertically-integrated specialty pharmaceutical company with expertise in the development, manufacturing and marketing of injectable pharmaceutical products, primarily used worldwide by hospitals. Sicor's finished dosage products manufacturing operations account for 32% of its total revenue, and is comprised of a portfolio of products that includes oncology, anesthesiology, and critical care. Sicor's 2001 revenues totaled nearly $370 million. According to its website, Sicor operates its business through several subsidiaries.

139. Defendant Gensia Sicor Pharmaceuticals, Inc. ("Gensia Sicor"), a Delaware corporation, is a wholly-owned subsidiary of Sicor with its principal place of business located at 17 Hughes, Irvine, California. Gensia Sicor focuses on acute-care multisource products in the fields of oncology, cardiology, and anesthesiology. Gensia Sicor's injectable drug business includes more than 60 products.

140. In 1999, Gensia Sicor entered into a sales distribution agreement with Abbott Laboratories under which the two companies formed a strategic alliance for the marketing and distribution of oncology products in the U.S. The agreement was restructured in March 2002. In 1999, Gensia Sicor also amended an earlier agreement with Baxter Pharmaceutical Products, Inc. Notably, Abbott (6%) and Baxter (34%) accounted for nearly 40% of Sicor's total product sales in 2001.

141. The drugs manufactured by Sicor, Gensia, and Gensia Sicor (collectively referred to as "The Sicor Group") and covered by Medicare Part B include, but may not be not limited to: amikacin sulfate and tobramycin sulfate.

19. TAP

142. Defendant TAP Pharmaceutical Products, Inc. ("TAP") is a corporation that arose in 1977 from a partnership between Takeda Chemical Industries, Ltd. and Defendant Abbott, under which each company owns 50 percent of TAP's stock. Abbott and Takeda jointly control TAP's operations and rotate control of TAP's presidency.

143. Prior to April 2000, TAP was known as TAP Holdings, Inc. TAP, together with its subsidiary, TAP Pharmaceuticals, Inc., develops and markets pharmaceutical products for the United States and Canada. TAP's headquarters is located in Waukegan, Illinois.

144. The pharmaceuticals manufactured by TAP include Lupron and Prevacid.

145. TAP is also sued herein for its role in the Together Rx Card Program.

20. Watson

146. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California. Watson develops, manufactures and markets brand and generic pharmaceuticals. Watson is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

147. The pharmaceuticals manufactured by Watson and covered by Medicare Part B include, but may not be limited to: albuterol sulfate, dexamethasone acetate, diazepam, gentamicin sulfate, iron dextran, testosterone enanthate, vancomycin hydrochloride, and cytarabine.

IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

148. The allegations contained herein apply generally to all Defendants.

A. The AWP System

149. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers.

150. Providers regularly submit claims for reimbursement, seeking payment for the drugs from Medicare, insurers and patients. During the Class Period, the Defendants were aware that the Medicare program and virtually all end payors (the latter are included as members of the Class) use published AWPs to reimburse providers for drugs. Use of the published AWPs to establish reimbursement rates for drugs is an industry-wide practice and exists with respect to all classes of drugs, brand name and generic and is used for Part B drugs and non-Part B drugs.

151. There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs on the market, including the *Drug Topics Red Book* (the "*Red Book*"), *American Druggist First Databank Annual Director of Pharmaceuticals* and *Essential Director of Pharmaceuticals* (the "*Blue Book*") and Medi-Span's *Master Drug Database* (collectively referred to herein as the "Publishers"). These Publishers publish AWPs for the various dosage forms for drugs. And the AWPs are published for Part B, non-Part B, brand name and generic drugs.

152. In periodically announcing the AWP for each drug, during the time period relevant to this Complaint the Publishers publish the prices that are supplied to them by the Defendant Drug Manufacturers for their respective drugs. For instance, the forward to the 1999 edition of the *Red Book* states that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the Defendant Drug Manufacturers control the prices listed as the AWPs for each drug listed by the Publisher.

153. A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers. The Defendant Drug Manufacturers knew they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP. The Defendant Drug Manufacturers also knew that actual transaction price data – the amounts charged to providers and others for their drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret.

154. As detailed, the AWPs for the drugs at issue here bore little relationship to the drugs' pricing in the marketplace. They were simply fabricated and overstated in furtherance of

Defendants' scheme to generate the profit spread to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members.

155. Plaintiffs and the members of the Class paid for the drugs based on the inflated AWPs reported by the Defendant Drug Manufacturers.

156. The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs (sometimes referred to herein as the "AWP Scheme") directly caused Plaintiffs and the members of the Class to substantially overpay for those drugs.

157. As detailed below, this overpayment manifested itself in two contexts, both of which were well known and understood by the Defendant Drug Manufacturers: (i) all drugs administered under Medicare Part B and (ii) drugs administered outside of the Medicare context whose reimbursement was established by use of AWP as a benchmark.

B. The Defendant Drug Manufacturers Commit AWP Fraud to Increase Market Share For Their Drugs Covered by Medicare Part B

1. The Medicare Insurance Program

158. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

159. The United States Department of Health & Human Services ("HHS") is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMMS"), formerly known as the Health Care Financing Administration ("HCFA"), is a division of HHS and is directly responsible for the administration of the Medicare Program.

160. The Medicare Program generally does not cover the cost of prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B.

161. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug. During the period 1992 through 1997, Medicare's reimbursement for Covered Drugs was set at the lesser of the estimated acquisition cost or national average wholesale price. For generic drugs (where more than one company sells a certain drug, sometimes called multiple-source drugs), payment was based on the lower of the estimated acquisition cost or the wholesale price that was defined as the median price for all sources of the generic form of the drug. This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

162. The estimated acquisition cost for a drug could be determined by the Medicare Program "based on surveys of the actual invoice prices paid for the drug" taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

163. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

164. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that reimbursement for certain Medicare Part B drugs and biologicals "are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span."

165. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP.

166. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable.

167. Some Medicare beneficiaries are able to purchase private Medigap insurance, which covers, among other things, all or part of the 20% co-payment for Covered Drugs.

168. In setting reimbursement rates, the Medicare Program uses the AWPs generated by the pharmaceutical industry. There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWPs directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWPs in trade publications, which are then used by the government, as well as private health plans.

169. The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar

> benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

170. And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to***

> ***induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.*** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

2. Congressional and Other Federal Investigations and Actions

171. The United States Department of Justice ("DOJ"), the United States General Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating the Defendant Drug Manufacturers and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWPs and for offering illegal incentives to providers.

172. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America (most of the Defendant Drug Manufacturers are members of this association), Congressman Stark identified the improper scheme of manipulating AWPs and noted:

> This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.

173. In his September 28 letter, Congressman Stark made the following five "shocking conclusions":

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
>
> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded

> health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
>
> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

174. The DOJ and Congressional investigations are ongoing.

3. Certain of the Defendants Drug Manufacturers' Fraudulent Conduct Within the Medicare Part B Program

175. As set forth below, certain of the Defendants Drug Manufacturers each perpetrated the alleged fraudulent scheme by using some and/or all of the following practices:

a. Artificially Inflating AWPs

176. Each Defendant Drug Manufacturer provided AWPs for each of its drugs to the *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia for Covered Drugs and non-Part B drugs, both brand name and generic.

177. During the Class Period, the Defendant Drug Manufacturers deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause Plaintiffs and the Class members to overpay for the Covered Drugs. The Defendant Drug Manufacturers created and perpetuated this scheme so that the medical providers who purchased these drugs at a low cost would bill patients and their insurers at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates.

178. The Defendant Drug Manufacturers knew and understood that Medicare and Plaintiffs and the Class members used the *Red Book* and other publications to determine the

AWPs of the drugs. Because the Defendant Drug Manufacturers controlled the AWPs published in the *Red Book* and other compendia, the Defendant Drug Manufacturers knew and understood that they could manipulate the providers' profits from Plaintiffs and the Class. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers, funded by Plaintiffs' and the Class members' overpayments.

179. As part of their scheme, the Defendant Drug Manufacturers specifically instructed and expected the providers to charge the inflated AWPs for Covered Drugs to Medicare, Plaintiffs and the Class members.

b. Improper Use of Free Samples

180. The Defendant Drug Manufacturers, through their sales personnel and marketing representatives, also provided free samples of their drugs to providers as a means of lowering the price. The free samples were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread." Moreover, the Defendant Drug Manufacturers specifically told providers to bill Plaintiffs and the members of the Class for the free samples, which Defendants knew was unlawful.

181. Every free sample of a drug for which a provider bills a patient or insurer effectively reduces that provider's overall cost for that drug. However, the full cost of the Covered Drug was charged to the Plaintiffs and the Class members, and the free sample is not used by the drug company in calculating the AWP, which in turn inflates the AWP.

182. Although the Defendant Drug Manufacturers provided free samples and marketed them as a way to lower the providers' actual cost of the Covered Drugs, they did not include the value of the free samples in calculating the AWPs for those drugs. Thus, the Defendant Drug Manufacturers effectively and improperly passed on the cost of the free samples directly to Plaintiffs and the members of the Class.

c. Other Hidden and Improper Inducements and Price Reductions

183. The Defendant Drug Manufacturers also have provided and/or arranged for many other non-public financial inducements to stimulate sales of their Covered Drugs at the expense of Plaintiffs and the members of the Class. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing the Defendant Drug Manufacturers' Covered Drugs. And again, the value of these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflates the AWP.

C. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain the Price of Drugs Outside of the Medicare Part B Context

184. The Defendant Drug Manufacturers' AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to reimbursements for scores of other drugs. As described below, one such area is the use of AWPs by PBMs.

185. Health plans typically contract with intermediaries called pharmacy benefit managers ("PBMs") so that a health plan's participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs. In these contracts, the brand name drugs are priced at the AWP less a certain percentage "discount."

186. Pharmacy benefit managers – or "PBMs" – are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBM clients include HMOs, employers, preferred provider organizations and other health insurers. Collectively, four PBMs comprise the significant market share of the PBM market. They are: AdvancePCS; Caremark; Express Scripts; and Medco Health. These four companies handle the drug benefits of 210 million people in the United States, or 70 percent of the nation's population.

187. For brand name drugs, PBMs use inflated "Average Wholesale Price" – or "AWP" – set by drug manufacturers as the basis for reimbursement (i) made by health plans to

the PBMs for their members' drug purchases; and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members. The PBMs typically contract with retail pharmacies to reimburse an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. However, the PBM frequently pockets a "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBM. Furthermore, as the example presented demonstrates, PBMs are motivated to, and do place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread. A similar situation occurs for generic drug pricing based on Maximum Acquisition Cost ("MAC") lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies. Further, with respect to mail order prescriptions, PBMs do business with companies that have the right to repackage drugs; they are called repackagers. These repackagers assign a new NDC number to a drug and publish a higher AWP. The PBM then negotiates with the repackager a discount off the AWP and tells the health plan it has saved a certain percentage off the AWP. But because the repackager's AWP is higher, the health plan pays more and the PBM pockets the spread between the AWP and the price paid to the repackager. PBMs also have mail order services in which case they act as the pharmacy. In this situation, the PBM keeps the spread between the AWP and the list price as there is no intermediary, like a pharmacy dispensing the drug. The PBMs keep this spread knowing that the AWPs are inflated and not the true AWP.

188. The Defendant Drug Manufacturers knew and understood that the PBM Defendants used the *Red Book* and other publications to determine the AWPs of the drugs.

Because the drug manufacturers controlled the AWPs published in the *Red Book* and other compendia, the drug manufacturers knew and understood that they could help manipulate the PBMs' profits from Plaintiffs and the classes. The purpose of artificially inflating the PBMs' profits was to create an illegal kickback to the PBMs, funded by health plan and subscriber overpayments.

189. PBMs use the inflated AWPs set by drug manufacturers as the basis for the payments (i) made by health plans to the PBMs for their members' drug purchases, and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members.

190. The PBMs typically contract with retail pharmacies to reimburse in an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies.

191. However, the PBMs frequently pockets a secret "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBMs.

192. Furthermore, as the example presented demonstrates, PBMs are motivated to place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread.

193. A similar situation occurs for generic drug pricing based on MAC lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies.

194. The PBMs deliberately utilize the inflated AWP to overcharge health plans for brand name drugs purchased by their participants and beneficiaries at retail pharmacies. An example of this practice was recently reported in the WALL STREET JOURNAL on March 30, 2003. According to the JOURNAL article, the AWP for fluoxetine is $2.66 a pill. With a 60 percent

discount off the AWP, that brings the price to $1.06 a pill the PBM collects from the plan. Express Scripts pays the pharmacy 25 cents a pill and keeps the rest as profit. Express Scripts claims that currently its client pays 60 cents a pill, but since Express Scripts pays a pharmacy 25 cents per pill, it receives almost a 100 percent profit. And at the same time it was making this profit, Express Scripts was notifying its clients it was saving them money by having switched to fluoxetine, instead of Prozac.

D. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain Volume and Market Share For Generic and Multi-Source Drugs

195. The Defendant Drug Manufacturers' AWP fraud is most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents.

196. Health plans and other sponsors of drug benefits contract with PBMs both so that the plan's participants can obtain ***brand name*** drugs from pharmacies or mail order distribution, but also so that they might receive ***multi-source***, or ***generic, drugs***. As with brand name drugs, reimbursement for multi-source, or generic, drugs is also related to a published average wholesale price for each generic drug manufactured and/or distributed by a generic drug company.

197. In the private payor arena, generic drug reimbursement is determined either in the same manner for brand name drugs (*i.e.*, a certain percentage "discount" off of the AWP), or is based on the amount specified as the maximum allowable cost or "MAC." MAC prices or reimbursements rates are a schedule of pricing for generically equivalent drugs based upon the listed average wholesale prices (AWPs) of competing generic drug manufacturers. The federal government originally introduced the concept of MAC reimbursement for generic medications. The CMS issues a MAC price list for generic products that have three or more manufacturers or distributors on the market. Because of this limitation, not all generics have a corresponding CMS MAC price.

198. PBMs often utilize this government-issued MAC reimbursement publication as a basis for their proprietary MAC list and supplement the list with other generic products or modify it for a variety of purposes. Sometimes, to stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate a maximum allowable cost based on the list average wholesale prices of competing generic drug manufacturers (indeed, this is termed in the industry as the average average wholesale price or "AAWP"). The resulting proprietary MAC generic drug reimbursement lists are typically based on the AAWP and, in turn, the AWP.

199. Accordingly, in the private payor arena generic drug reimbursement is closely tied to the published AWP for a generic drug. Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain. That profit margin is taken advantage of either directly (through reimbursement based upon the AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a MAC tied to the AWP.

200. In the public payor arena under Medicare Part B, multi-source drugs or biologicals are also reimbursed on the basis of AWP. For multi-source drugs or biologicals, under Medicare Part B the AWP is equal to the lessor of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicare Part B, including the Medicare co-payment through Part B.

201. As stated by one industry consultant:

> . . . This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs.. . . [T]he system allows a retailer to acquire a drug at a low cost $2.50 per 100

> tablets, for example) while relying on a published AWP ($20.00 or more) for its own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines. . . .It is obvious that AWP is not an accurate measure of the prices manufactures charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits.

202. The raising of an individual Defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed. As a result, the publication and reporting of fraudulent AWPs by Defendants for generic drugs squarely fits generic drugs in which the cure of unlawful AWP inflation within the activity complained of in the MCC. Moreover, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.

203. Documents produced by Defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

Defendant	Multisource Drug	*RedBook* AWP	DOJ Determined Actual AWP	Percentage Spread
Abbott	Sodium Chloride	$670.89	$3.22	20,735%

Defendant	Multisource Drug	*RedBook* AWP	DOJ Determined Actual AWP	Percentage Spread
Baxter	Dextrose	$928.51	$2.25	41,167%
Baxter	Sodium Chloride	$928.51	$1.71	54,199%
Boehringer Group	Leucovorin Calcium	$184.40	$2.76	6,581%
B. Braun	Sodium Chloride	$11.33	$1.49	660%
BMS Group	Etoposide (Vepesid)	$136.49	$34.30	298%
Dey	Albuterol Sulfate	$30.25	$9.17	230%
Immunex	Leucovorin Calcium	$137.94	$14.58	846%
Pharmacia	Etoposide	$157.65	$9.47	1,565%
Sicor Group	Tobramycin Sulfate	$342.19	$6.98	4,802%
Watson	Vancomycin HCL	$70.00	$3.84	1,567%

204. In summary, generic or multi-source drugs are subject to fraudulent AWP manipulation as set forth in this Amended MCC.

205. The importance of AWPs to generic drugs was recently revealed in a lawsuit filed by Dey and two of the Publishers. In this lawsuit, Dey's allegations can be summarized as follows:

(a) Dey is a generic manufacturer, and generic manufacturers largely compete on price because they market products that contain the same active ingredients and are predominantly therapeutically interchangeable. (¶ 9 of Dey Complaint.)

(b) A large segment of the generic marketplace for respiratory drugs is comprised of a relatively small number of entities controlling purchase decisions. (¶ 12 of Dey Complaint.)

(c) The vast majority of prescription drug transactions – as much as 85% – are covered, in whole or in part, by third-party payor reimbursement arrangements such as managed care plans and Medicaid. (¶ 13 of Dey Complaint.) Both Medicaid and the private insurance system rely on reimbursement formulas that utilize the AWP. (¶¶ 14-16 of Dey Complaint.)

This allegation confirms Plaintiffs' allegations in this Complaint that the AWP fraud impacts private markets, not just Medicaid.

(d) Dey has an agreement with First DataBank and Medi-Span to provide the reporting services with AWP pricing information. Pursuant to this agreement (and in order to make Dey's products eligible for reimbursement through Medicaid Programs), Dey has reported WACs and AWPs. (¶¶ 26-32 of Dey Complaint.)

> In each case, until the events that have resulted in the present crisis, First DataBank has (except for some inadvertent errors) selected for listing in its published reports the AWP as suggested by Dey. For over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First DataBank as AWP for Dey products in its databases [even though Dey also reported declining WACs for the products]."

(¶ 32 of Dey Complaint; *see also* ¶ 36 of Dey Complaint for similar allegation against Medi-Span.) This has also been the course of dealings between the Publishers and Dey's competitors:

> Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey's knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

(¶ 37 of Dey Complaint.) *See also* ¶ 47 of Dey Complaint (recounting testimony of First DataBank representative who admits that First DataBank had always accepted the AWPs suggested by the manufacturers).

(e) Providers who dispense generic drugs "are cognizant of, and are highly attentive to, AWPs as reported by the recognized industry compendia published by First DataBank and Medi-Span because of the direct relationship between the level of reimbursement anticipated for the drugs selected and the reported AWPs of those drugs." (¶ 38 of Dey Complaint.) Indeed, Dey admits that it has relied on the publishers' practice of treating all manufacturers equally by simply reporting whatever AWP a manufacturer submitted.

Consequently, First DataBank and Medi-Span have frustrated Dey's "reasonable expectations" by ***independently reporting*** an AWP different than that submitted by Dey. (¶ 39 of Dey Complaint.) These allegations become even more emphatic in a section of the Complaint titled "The Immediate Consequences of the Arbitrary Changes:"

> Since reimbursement to Dey's customers is, in Medicaid program in many states and in and [sic] insurance programs, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. Since there has not been a comparable reduction in the AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.
>
> Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.
>
> In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.
>
> Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.
>
> ..... These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

(¶¶ 50-54 of Dey Complaint.)

206. ***These allegations confirm the allegations herein that medical providers rely on spreads in dispensing (and, consequently, so do the manufacturers in order to move market***

share). Further, these allegations are akin to saying: "We all committed fraud on an even basis, but now only my competitors can commit fraud; consequently, I have now suffered damage."

E. Defendants' Concealment of the Truth

207. Each Defendant concealed its fraudulent conduct from the Plaintiffs and the Class by controlling the process by which the AWPs for Covered Drugs and brand name drugs were set. Defendants prevented Plaintiffs and the Class Members from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, Defendants' fraudulent conduct was of such a nature as to be self-concealing.

208. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs and brand name drugs. CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug "price discounts are closely guarded as competitive information." *See* p. 39.

209. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs and brand name drugs, respectively.

210. Each Defendant also worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

211. Each Defendant's efforts to conceal its pricing structures for Covered Drugs and brand name drugs is evidence that it knew that its conduct was fraudulent.

212. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the AWPIDs), (ii) it was manipulating the AWPs of the AWPIDs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the AWPIDs as they were sold to providers and others.

213. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice nor learn of the factual basis for their claims in this Complaint and the injuries suffered therefrom until recently.

F. Tolling of Applicable Statutes of Limitation

214. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and members of the Class have been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of the published AWPs.

215. Defendants were and continue to be under a continuing duty to disclose to Plaintiffs and the Class the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs and brand name drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, Defendants are estopped from relying on any statutes of limitations.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

216. Due to acts of concealment by each Defendant, the following examples of the specific unlawful conduct engaged in by each particular Defendant are merely illustrative. They are not intended to be an exhaustive account of all of the unlawful activity engaged in by each Defendant. Instead, these allegations allege the circumstances of the wrongdoing with some detail. Additional detail is peculiarly within the Defendants' control and warrants that further discovery should proceed as to each drug identified in this Complaint as well as other drugs whose AWP is published by any Defendant.

A. Abbott

217. Abbott engages in an organization-wide and deliberate scheme to inflate AWPs. Abbott has stated fraudulent AWPs for all or almost all of its drugs, including those set forth

below. The specific drugs of Abbott for which relief is currently sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (If applicable)	Generic Name	Therapeutic Category/Usage
ABBOTT	A-Methapred	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used for control of allergic processes
	Aminosyn	amino acid	Nitrogen Product Used as a nutritional supplement
	Biaxin	clarithromycin	Macrolide (Anti-Infective Agent) Used to treat mild to moderate infections
	Calcijex	calcitrol	Hormone Used in the treatment of hypocalcemia
	Depakote	divalproex sodium	Anticonvulsant Used in the treatment of complex partial seizures
	Ery-tab	erythromycin, enteric-coated	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various infections
	Erythromycin	erythromycin base	Antiacne Agent; Anti-Infective Agent Used in the treatment of various infections
	Liposyn II	fat emulsion	Caloric Agent; Nutritional Supplement Used as a nutritional supplement
	Prevacid	lansoprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of duodenal ulcer and erosive esophagitis
		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cimetidine hydrochloride	Gastrointestinal Agent Used in the treatment of duodenal ulcer and prevention of ulcer recurrence
		clindamycin phosphate	Anti-Infective Agent Used in the treatment of vaginal infections
		dextrose	Caloric Agent Used to increase intake of calories and fluids

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		dextrose sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		diazepam	Central Nervous System Agent Used to treat status eplipeticus and anxiety disorders. Also used as an amnesic prior to surgical procedures
		fentanyl citrate	Central Nervous System Agent Used for anesthetic purposes
		furosemide	Diuretic Used in the treatment of edema associated with cirrhosis and kidney disease. Also used to manage hypertension
		gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
		heparin sodium or heparin lock flush	Blood Modifier Used to prevent and treat thrombosis and pulmonary embolism. Also used as an anticoagulant in blood transfusions and dialysis procedures
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		lorazepam	Central Nervous System Agent Used in the treatment of anxiety disorders
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		tobramycin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat severe infection
		vancomycin hydrochloride	Antibiotic Agent (Anti-Infective Agent) Used as a general antibiotic

1. Abbott Has Been The Target of Government Investigations

218. In connection with its scheme to inflate AWPs, Abbott has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

219. These investigations confirm that Abbott has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. According to Representative Pete Stark, the ranking member of the Congressional Ways and Means Committee:

> The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to . . . as "the spread." The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

See October 31, 2000 letter from U.S. Representative Pete Stark to Miles White, Chief Executive Officer of Abbott. (P007647-78.)

2. Abbott Controls the Published AWP for Its Products

220. Abbott has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

3. Abbott's AWP Manipulation Benefited Providers at the Expense of the Class

221. The purpose of Abbott's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. For example, Abbott anticipated that the spread between AWP and cost would be eliminated by legislative changes in 1997. Accordingly, Abbott looked for ways to maximize the profit spread immediately. In one internal memorandum about a third party's pricing product, Abbott states:

> One of GeriMed's goals of obtaining maximum profitability for its members presents an opportunity for our injectables. They think there is about an 18 month window of opportunity to promote our injectables as more profitable for their members to use because of the bigger spread between AWP and cost. Legislative changes in reimbursement are expected to do away with this spread advantage by mid 1997.

(ABT AWP/MDL 015839) (Highly Confidential).

b. In a second memorandum about this same product, Abbott states:

> The purpose of these programs was to "enhance revenue and decrease cost." *** These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price.... The [distributor's] program identifies the lowest cost product and ***the best spread for the particular state***.

(ABT AWP/MDL 010407-09) (Highly Confidential) (emphasis added).

222. Abbott tried to maximize spread because it understood that its customers routinely engaged in "spread shopping" – comparing Abbott's AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread). An example is a document produced by Abbott, prepared by a customer in late 1993, comparing Abbott's proposed contract price and its published AWPs with that of Baxter's competing generic drugs. (ABT AWP/MDL 028546) (Highly Confidential).

223. Just as Abbott motivates providers to administer drugs based on the AWP, Abbott's 1996 Pricing Guidelines reveal that Abbott rewards PBMs based on the degree of influence they exert to drive utilization of Abbott products. (ABT AWP/MDL 053922-23) (Highly Confidential).

4. Specific Abbott AWPs Documented by the DOJ

224. In a report published by the DHHS (the "DHHS Report"; PM Rev. AB-00-86, "An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program," Sept. 8, 2000), the DOJ documented at least 81 instances where the published AWPs for various dosages of 16 drugs manufactured by Abbott were

substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 16 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Abbott's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acetylcysteine	$35.87	$21.90	$13.97	64%
Acyclovir	$1047.38	$349.05	$698.33	200%
Amikacin Sulfate	$995.84	$125.00	$870.84	697%
Calcitriol (Calcijex)	$1,390.66	$1079.00	$311.66	29%
Cimetidine Hydrochloride	$214.34	$35.00	$179.34	512%
Clindamycin Phosphate	$340.52	$75.35	$265.17	352%
Dextrose	$239.97	$3.91	$236.06	6,037%
Dextrose Sodium Chloride	$304.38	$1.93	$302.45	15,671%
Diazepam	$28.50	$2.03	$26.47	1,304%
Furosemide	$74.52	$14.38	$60.14	418%
Gentamicin Sulfate	$64.42	$.51	$63.91	12,531%
Heparin Lock Flush	$38.30	$13.60	$24.70	182%
Metholprednisolone Sodium Succinate	$34.08	$2.30	$31.78	1,382%
Sodium Chloride	$670.89	$3.22	$667.67	20,735%
Tobramycin Sulfate	$150.52	$2.94	$147.58	5,020%
Vancomycin Hydrochloride	$382.14	$4.98	$377.16	7,574%

(P006299-316.)

5. Additional Evidence Concerning Vancomycin

225. At least one Publisher, Medi-Span, challenged the manner in which Abbott set its AWPs for vancomycin. The following statement appeared in a February 9, 1996 faxed letter to Abbott from a representative of Medi-Span:

> It appears that the only difference between these two products listed is the vial it comes in. If it is, please let us know why the $400 plus difference in AWPs?... [T]his customer claims he can get Vancomycin for $6 or $7 per vial DP as opposed to the $52.94 and $19.50 the Abbott Vancomycin cost.

(ABT AWP/MDL 001215.)

226. The government investigation into Abbott's AWP for vancomycin identified:

> prices that are routinely made available to many providers, but are far below Medicare reimbursement rates. They include 1999 prices for vancomycin, the Abbott Labs-manufactured antibiotic, which a health care provider could buy for $76.00 but for which the AWP upon which Medicare's reimbursement was based on was $261.84.

See September 25, 2000 letter from U.S. Rep. Tom Bliley to the Honorable Nancy-Ann Min DeParle, Administrator of the Health Care Financing Administration. (P007015-490.)

227. For other doses of vancomycin, Abbott reported an AWP of $68.77 as of April 2000. The DOJ adjusted it to $8.14.

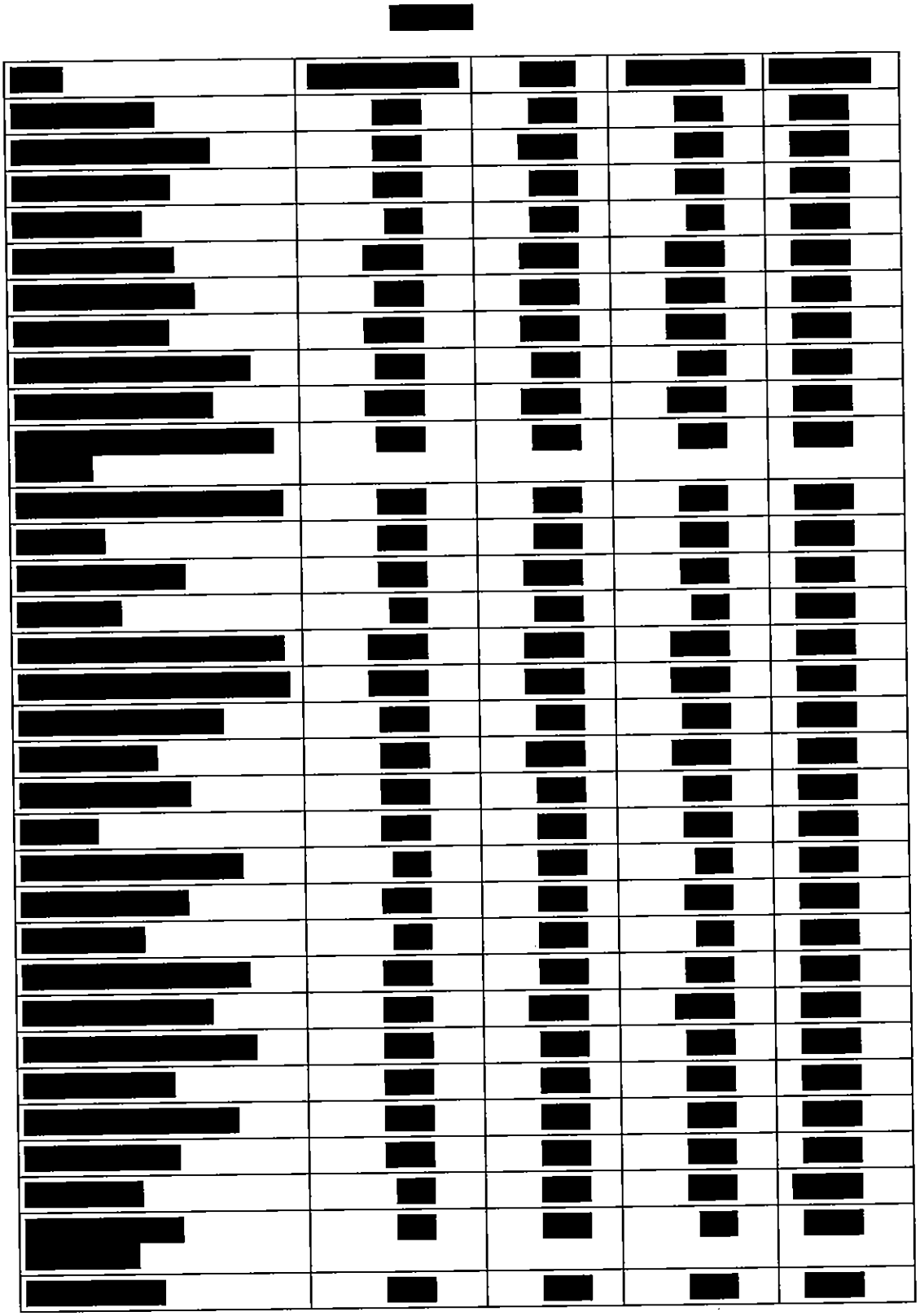
6. Additional Evidence for Amikacin

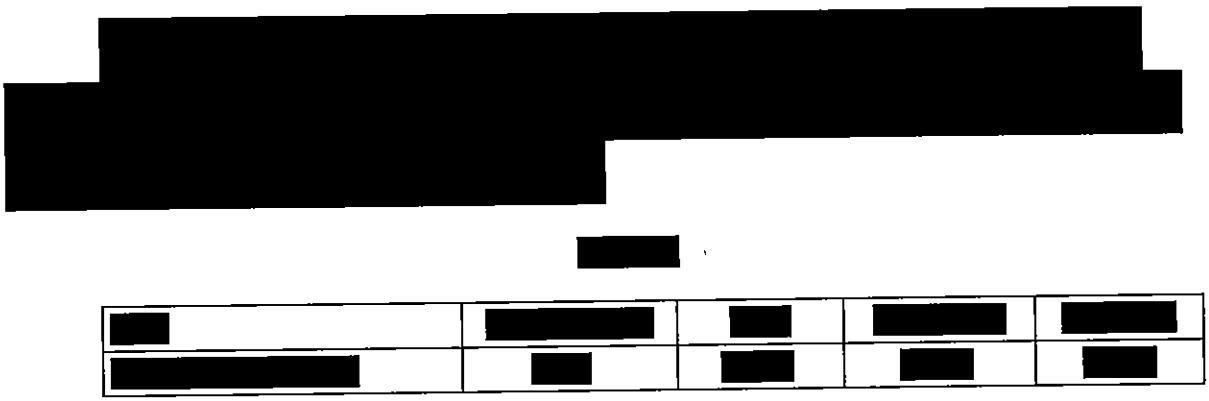
228. One published report states: "Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of $54.56. DOJ said the actual price was $6.75." *See States Mull Suit Against Drug Companies*, www.stateline.org (April 2, 2001) (P011268-70).

7. Inflated AWPs From Abbott Price Lists

229. In response to government subpoenas, Abbott produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Abbott has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads in excess of 100% from two specific Abbott customers.

230. [redacted]





232. As set forth above, Abbott's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

B. Amgen

1. The Drugs at Issue and Their Competitive Environment

233. Amgen engages in an organization-wide and deliberate scheme to inflate AWPs. Amgen has stated fraudulent AWPs for all or almost all of its drugs, including: Epogen (eportin alfa for ESRD use),[1] Neupogen (filgrastim), Aranesp (darbepoetin alfa), Enbrel (etanercept), Kineret (anakrina), and Neulasta (pegfilgrastim). The specific drugs of Amgen for which relief is sought in this case are set forth in Appendix A and are set forth below and the complaint includes all NDCs for these drugs:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AMGEN	Aranesp	darbepoetin alfa albumi	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure and/or chemotherapy
	Enbrel	etanercept	Antirheumatic Agent Used to reduce signs and symptoms of rheumatoid arthritis

[1] In the Medicare Part B context, reimbursement for Epogen is not based on the AWP, but rather on a specific dollar amount set by statute. However non-Medicare Part B reimbursement for Epogen is based on AWP for many Class members.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Epogen	epoetin alfa	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure, chemotherapy and/or HIV-infected patients
	Kineret	anakrina	Antirheumatic Agent Used in the treatment of moderate to severe rheumatoid arthiritis
	Neulasta	pegfilgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer patients
	Neupogen	filgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer and leukemia patients

224A. Amgen introduced EPOGEN® (Epoeitin alfa) in 1989. EPOGEN® is indicated for the treatment of anemia in patients with chronic renal failure on dialysis. In 2001, Aranesp® (darbepoetin alfa), an erythropoietic protein with greater biological activity and a longer half-life than Epoetin alfa, was approved for the treatment of anemia in patients with chronic renal insufficiency. In 2002, Aranesp® was also approved for the treatment of chemotherapy-induced anemia. By 2003 Aranesp had sales of $283 million.

224B. NEUPOGEN® (filgrastim) was approved in 1991. NEUPOGEN® is indicated for decreasing the incidence of infection associated with chemotherapy-induced neutropenia in cancer patients with nonmyeloid malignancies. In 2002, Amgen introduced Neulasta® (pegfilgrastim), a longer-acting form of filgrastim approved for the same use but requiring only one injection per chemotherapy cycle.

234. Since its introduction, Aranesp has been locked into a knock-down competitive battle with Ortho Biotech's Procrit.

225A. A review of their respective websites reveals that Amgen and Ortho are targeting the exact same type of patient with respect to use of Aranesp and Procrit. Amgen describes Aranesp on its website as follows:

> That's where Aranesp® can help. Aranesp® stimulates natural production of red blood cells boosting the number of red blood cells in the body, which can increase the amount of oxygen in your blood and give you more energy. And since you will need fewer shots and doctor visits, you can begin to feel less like a patient and more like a person – and get back to being you again.
>
> Aranesp® is available by prescription only. Aranesp® has been approved by the Food and Drug Administration to treat the anemia associated with chronic renal failure (renal disease) in people with reduced kidney function or on dialysis. People who have uncontrolled high blood pressure should not use Aranesp®.

225B. Ortho promotes and describes Procrit on its website as follows:

> PROCRIT® (Epoetin alfa) is for the treatment of anemia in patients who have chronic kidney disease and are on dialysis. PROCRIT has a proven safety record. Your doctor should carefully monitor your blood pressure and hemoglobin for rapid increases, which should be avoided. PROCRIT is available by prescription only and is administered by your health care provider.

(Emphasis added).

235. Thus, these two companies were targeting the exact same patients and have an incentive to compete based on the spread that they could offer physicians.

226A. Amgen's Neupogen also competed with Immunex's Leukine prior to Amgen's acquisition of Immunex. Both of these drugs are Part B covered drugs and as set forth below this competitive landscape became a breeding ground for competition based on spread or discounts off AWP. Competition also existed between Amgen's Remicade and Immunex's Embrel, which created a climate for using the spread between AWP and acquisition cost as an inducement to wholesalers and other providers.

2. Amgen's Definition and Understanding of AWP

226B. Internally, Amgen defines AWP as "the common basis for reimbursement by payors. AWP may not necessarily reflect the actual purchase price" (Press Release, "Data from Study Shows Aranesp …," Dec. 9, 2002 (www.amgen.com)) or "one of the factors used by Medicare to determine payment for drug charges."

3. Amgen Controls the Published AWP for Its Products

236. Amgen has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

4. Amgen Understands the Importance of Reimbursement Rates

227A. Amgen was well aware that its customers' profits depended on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depended on its customers' reimbursement payments and profits:

> Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.
>
> In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors ... ***we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies***. ... If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues ...

(Amgen 2002 Form 10-K at 43-44).

227B. The foregoing references referring to "reimbursement policies" refers to policies that use AWP as the benchmark for reimbursement.

237. Amgen also made sure its sales representatives were focused on reimbursement and customer profit motives. A senior Amgen sales manager has publicly stated:

> Reps need to understand the insurance system flawlessly. They need to understand the money trail in terms of how a drug gets reimbursed, who reimburses it, and coverage or policy limitations – those are fundamental questions."

228A. Part of that "understanding" was an explanation by Amgen sales representatives that was routinely made by sales representatives to physicians concerning profit that a physician could make by purchasing at a discount off AWP. With respect to, for example, Aranesp and

Neupogen, Amgen sales representatives either handed out calculations showing the spread off of AWP that a provider could realize by using Amgen's drugs, or orally reviewed such profits with physicians.

228B. Amgen has also established a website (www.reimbursementconnection.com) to help providers with reimbursement issues, including information on how to calculate reimbursement for Amgen drugs and Sample Reimbursement Sheets detailing how much Medicare will pay for Amgen drugs. In addition, Amgen maintains a telephone Reimbursement Hotline for providers or their office staffs to call to get help with reimbursement questions.

238. Amgen actually promotes the use of AWPs for reimbursement purposes on its website as follows:

Sample of Reimbursement Payments for Aranesp® Syringe/Vial Strengths

		Medicare		
Syringe/Vial Strength	**Average Wholesale Price (AWP)[1/2]**	**85% of Medicare Allowable (AWP)**	**Payment[1] (at 80%)**	**Secondary Insurer or Patient Co-Payment[2] (at 20%)**
J0880 – 25 mcg*	$124.69	$105.99	$84.79	$21.20
J0880 – 40 mcg*	$199.50	$169.58	$135.66	$33.92
J0880 – 60 mcg*	$299.25	$254.36	$203.49	$50.87
J0880 – 100 mcg*	$498.75	$423.94	$339.15	$84.79
J0880 – 150 mcg**	$748.13	$635.91	$508.73	$127.18
J0880 – 200 mcg*	$997.50	$847.88	$678.30	$169.58
J0880 – 300 mcg*	$1,496.25	$1,271.81	$1,017.45	$254.36
J0880 – 500 mcg†	$2,493.80	$2,119.73	$1,695.78	$423.95

[1] As reported in *Drug Topics Red Book®*, February 2004.
[2] Most private insurers base reimbursements for drugs on a percentage above or below published AWP.
* These strengths are available in either Arenesp® SingleJect® prefilled syringes or vials.
† Available only in Aranesp® SingleJect® prefilled syringe.
** These strengths are available in vials only.

229A. In the above table, Amgen recognizes the impact of an AWP-based price on a "secondary insurer" or patient making copay. Amgen thus promotes AWP all the while knowing that the posted AWP is artificially inflated as described.

5. Specific Examples of AWP Abuse

229B. At all relevant times Amgen understood that reimbursement for its drugs was dependent upon AWP. Amgen set the AWPs for its products in an arbitrary manner that rendered AWP to be a fictitious number in that it failed to account for rebates, volume discounts and other incentives provided to physicians and others purchasing Amgen drugs.

239. Both Procrit and Aranesp are Part B covered drugs, hence given the competition between the two, one clear way to increase market share was to increase the spread and hence the profit to providers. Indeed at Aranesp's launch to the oncology market Amgen sales representatives had ready at their fingertips information concerning Aranesp's AWP, the Medicare reimbursement amount, WAC, WAC minus discounts and the "profit" created by the spread between Medicare reimbursement and net acquisition cost.

230A. It was intended by Amgen's top sales executives that its sales force would use this "profit" as a basis for marketing Aranesp.

230B. Examples of the improper use of AWPs by Amgen are set forth below. For example, to increase its market share Amgen in 2003 offered Aranesp to customers with a rebate or discount of up to 30% off of list price, which in itself is 20%-25% off of the published AWP. Thus, Amgen was offering spreads of 50% or more off of the published AWP on Aranesp. These spreads are being offered while Amgen is promoting use of AWP on its own website.

240. On or about July 18, 2003, Amgen extended this discount through July 15, 2004. Thus, even in the face of this litigation, Amgen was offering substantial discounts which rendered the reported AWPs inflated and without basis.